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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,562	11/16/2000	Eva Grahn Hakansson	48384-61007	4905

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/623,562

Applicant(s)

Hakansson

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 10, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3-9, and 12-23 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, and 12-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the spelling of "phamaceutical" in claim 15, and in the omission of "has" before "been" at line 3 in claims 1, and 7.

The processing of this application can be expedited by providing the following information or changes in your next amendment:

- A descriptive title (M.P.E.P. 606 and 606.01). Note 1-2 world titles are generally not acceptable.

The amendment filed 6/10/02 is acknowledged. Claims 1, 3-9 and 12-23 are being considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 112*

#### INDEFINITE

Claim 5-9 and 12-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 8, 12 are confusing in the recitation "LB931". For clarification, it is recommended that --*Lactobacillus plantarum*-- be inserted before "LB931".

In claim 9 "parmaceutical" should be replaced with "parmaceutically" for consistency and proper antecedent basis.

Regarding claim 9, the phrase "or other form" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or other form"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). In addition, it is unclear what is intended by "form" and "lactobacillus growth factor" in this context.

Also, the components of the composition should be set forth in the body of the claim, not in the preamble. See, e.g., claim 15, wherein the "pharmaceutical composition" is recited in the preamble.

Claims 16, 18, 19, 23 fail to find proper antecedent basis for compositions or products in claims 15, 17, 22 which are method claims.

Claim 16 is confusing in the recitation "a colonization". It is unclear what is intended.

Claim 21 is vague and indefinite in the recitation "via a pharmaceutical composition".

Generally, administration is oral, parenteral, topical, etc. See also claim 22.

Claims 1, 3-9, 12-16, and 20-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reid *et al.* (US 5645830) for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a composition comprising *Lactobacillus plantarum* DSM 11918.

Reid *et al.* discloses compositions comprising *L. plantarum* ATCC 55883 (RC-20) and skim milk used for the prevention of urogenital infections. The composition may be freeze dried, or a cream, gel, liquid or suppository (col. 3, l. 25).

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' strain differs and, if so, to what extent from the strain discussed in the references. Accordingly, it has been established that the prior art *L. plantarum* ATCC 55883, which has the same genus and species designation and shares the property of being able to inhibit enterobacteria, adheres to epithelial surfaces in the urogenital region, etc. demonstrates a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Upon clearly distinguishing the applicants' claimed strain from the cited prior art strains, the claims may be found to be directed to patentable material.

Claims 17-19 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reid *et al.* ( US 5645830) as applied to claims 1, 3-9, 12-16, and 20-21 above, and further in view of WO 97/02846 [N].

The claims are further directed to a composition comprising *L. plantarum* DSM 11918 and an absorbent article.

WO 97/02846 discloses the composition comprising *L. plantarum* and an absorbent article such as a diaper.

The substitution of *L. plantarum* ATCC 55883 disclosed in the references of Reid *et al.* for the generic *L. plantarum* disclosed in the compositions of WO 97/02846 would have been obvious because it is the substitution of equivalents in the absence of evidence to the contrary.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

#### ***Response to Arguments***

Applicant's arguments and Isaksoon declaration have been fully considered but they are not deemed to be persuasive.

The declaration is persuasive regarding strain ATCC 8014. However it is not sufficient to overcome the rejection over strain ATCC 55883.

It is noted from the Isaksson declaration and the letter from Promochem that applicants were unable to obtain strain ATCC 55883. However, it is not clear whether the request was made to the American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209, where the respective strain was deposited. Therefore, the status of the availability of this strain and the meaning of "regulatory hold" cannot be ascertained.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx  
Primary Examiner  
Art Unit 1651